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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/531,517	04/15/2005	Simon Charles Goodacre	T1596P	9087

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EXAMINER

HABTE, KAHSA Y

ART UNIT PAPER NUMBER

1624

DATE MAILED: 04/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/531,517

Applicant(s)

GOODACRE ET AL.

Examiner

Kahsay Habte

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 16 is/are allowed.
- 6) ☒ Claim(s) 11-15 and 17-19 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4/15/2005</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 11-19 are pending in this application.

Information Disclosure Statement

2. Applicant's Information Disclosure Statement, filed on 04/15/2005 has been acknowledged. Please refer to Applicant's copies of the 1449 submitted herewith.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 18-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 18-19, it is recited a method of treatment or prevention of anxiety, convulsions or cognitive disorders, but the specification is not enabled for such a scope.

In evaluating the enablement question, several factors are to be considered. Note *In re Wands*, 8 USPQ2d 1400 and *Ex parte Forman*, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or

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absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

Claims 18-19 are directed to a method of treatment and prevention for anxiety, convulsions or cognitive disorders. The instant claims cover 'diseases' that are known to exist and those that may be discovered in the future, for which there is no enablement provided. There is no working example or any biological data to support applicant's claim. There is no test procedures or assays that are provided in the specification. There is no *in vitro* data correlate to the treatment of the diverse disorders embraced by the instant claims. The disorders encompassed by the instant claims (i.e. anxiety, convulsions and cognitive disorders), some of which have been proven to be extremely difficult to treat. There is no reasonable basis for assuming that the myriad of compounds embraced by the claims will all share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same. Note *In re Surrey*, 151 USPQ 724 regarding sufficiency of disclosure for a Markush group.

The claims are drawn to 'treating or prevention **cognitive disorders**'; however, cognitive disorders are very broad and extremely different one from the other. See below.

Cognitive Disorders – are disorders in a brain that prevents someone from thinking well, from solving problems, or from storing information. Three main types of cognitive disorders are: Delirium, Dementia, and Amnesia.

Delirium - is a severe disturbance in consciousness and thought that is not better accounted for by dementia. Delirium is likely to have a sudden onset, be variable, and have a better chance of remission than dementia. Delirium involves disorientation and memory loss, along with distorted consciousness and cognitive deficits. The victim may not know what time it is, or where she or he is, or be able to speak coherently. Short-term memory loss is almost always noted. The patient is usually agitated, with the agitation worse at night; if in the hospital, the patient may fight, break things or tear out intravenous tubes, and have to be restrained. The onset of delirium is typically fairly sudden, taking a few hours to a few days, and delirium rarely lasts for more than a month; unfortunately, one reason for this is that the patient may die. Especially for this reason, the occurrence of delirium is a clear medical emergency calling for prompt treatment. One cause of delirium is substance intoxication via overdoses of drugs or exposure to toxins, or withdrawal from drugs. Another is various medical conditions, brain trauma caused by an accident or stroke, for example. The type of delirium is determined by what caused it; for example, two types are substance intoxication delirium and delirium caused by a medical condition.

If intoxication or treatable medical problems are detected and treated, the delirium is probably reversible. If treatment is not possible, permanent brain damage is either present or likely to develop, and the delirium may progress to dementia.

Delirium can be subcategorized into one of the following depending on the causes:

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From substance intoxication

From withdrawal

From multiple causes

Other cognitive disorders include autism, ADHD, schizophrenia, and other forms of psychosis.

Dementia, like delirium, involves cognitive deficits, but the deficits are different. One universal characteristic of dementia is short-term memory loss. It may be accompanied by inability to find words (aphasia), to recognize objects (agnosia), or to carry out a sequence of motor activities (apraxia), despite the ability to make the individual movements. The onset of dementia tends to be more gradual than the onset of delirium, and may go unnoticed for long periods. The person with dementia may behave quite inappropriately, for example by telling dirty jokes to strangers or exposing genitalia. Violent behavior, although less common than in cases of delirium, sometimes occurs. In early cases of dementia, when the individual is aware of his or her deteriorating condition but still able to execute plans, suicide is a possibility.

Just as in delirium and many other disorders, the subtypes of dementia are classified according to their causes. An increasingly common type of dementia is dementia of the Alzheimer's type; estimates place the percentage of people over 65 in the United States with Alzheimer's at 2 to 4 percent.

Despite the fact that many causes of dementia are age-related, one should not assume that dementia is a normal consequence of aging. Although little can be done to prevent

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or ameliorate dementia in many cases, a medical examination is necessary in order to evaluate causes and possible treatments. One study of cases of dementia at three centers showed that 26% of the cases were treatable. The most common treatable cases are those with chronic drug toxicity, major depression, normal pressure hydrocephalus, or operable brain masses.

Future research may uncover, one type at a time, ways to prevent or treat the dementias; some drugs already show promise in arresting the progress of Alzheimer's disease. Other types of dementia include: Alzheimer's Disease, Creutzfeldt-Jacob Disease, HIV Dementia, Pick's Disease, Vascular Dementia, Substance-Induced Persisting Dementia, Dementias that can arise from head trauma, Huntington's Disease, Parkinson's disease, etc.

Amnesia - is loss of memory; it is retrograde if memories before a fixed event are lost, and anterograde if memories after a fixed event are lost. An individual may have both kinds of amnesia.

Amnesias, as the name indicates, are characterized by memory losses without sufficient cognitive deficits to indicate a diagnosis of delirium or dementia, and can be subcategorized into those: Caused by medical conditions, Caused by substance abuse, etc.

It is shown above that cognitive are broad in nature and the disorders vary one from the other. The burden is on applicants, to show that their compounds can treat the disorders that are listed above.

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The nature and type of **convulsions** (seizures) are also different one from the other.

Seizures have a wide variety of possible symptoms, depending on what parts of the brain are affected. Many types of seizures cause loss of consciousness with twitching or shaking of the body. However, some seizures consist of staring spells that can easily go unnoticed. Occasionally, seizures can cause temporary abnormal sensations or visual disturbances. Seizures can generally be classified as either "simple" (no change in level of consciousness) or "complex" (change in level of consciousness). Seizures may also be classified as generalized (whole body affected) or focal (only one part or side of the body is affected).

Thus, factors such as "sufficient working examples", "the level of skill in the art" and "predictability", etc. have been demonstrated to be sufficiently lacking in the use of the invention. In view of the breadth of the claim, the chemical nature of the invention, the unpredictability of ligand-receptor interactions in general, and the lack of working examples regarding the activity of the claimed compounds, one having ordinary skill in the art would have to undergo an undue amount of experimentation to use the invention commensurate in scope with the claims.

In regard to the prevention, to this day no one was able to achieve preventing healthy patients from anxiety, convulsions or cognitive disorders. It is recommended that applicants delete claims 18-19 to overcome this rejection.

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MPEP 2164.01(a) states, "A conclusion of lack of enablement means that, based on the evidence regarding each of the above factors, the specification, at the time the application was filed, would not have taught one skilled in the art how to make and/or use the full scope of the claimed invention without undue experimentation. *In re Wright*, 999 F.2d 1557,1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)." That conclusion is clearly justified here.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-15 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

a. In claim 11, the term "hydrocarbon" is not clear. What is it? Literally, it means a compound composed of carbon and hydrogen atom. What do applicants intend? What is covered by the term and what is not? Does it cover aliphatic hydrocarbons or carbocyclic? The specification at page 3 does not clearly define what said term mean. Note that alkyl, alkenyl, alkynyl and carbocyclic are acceptable.

b. Claims 12-15 and 17-19 are rejected because they depend from a cancelled claim 1.

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Allowable Subject Matter

5. Claim 16 is allowed.

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (571) 272-0667. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Wilson can be reached at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kahsay Habte
Primary Examiner
Art Unit 1624

KH
April 10, 2006